REMARKS

Claims 1-6 and 28-31 were pending in the present application. Claims 4 and 5 have been amended herein. Claims 11 and 13-27, which were indicated as being withdrawn, have been canceled herein without prejudice to their presentation in another application. No new matter has been added. Upon entry of the present amendments, claims 1-6 and 28-41 will be pending.

As a preliminary matter, claim 4 has been amended to recite that the composition comprises one or more "co-stimulatory molecules or cytokines." Support for this amendment can be found at, for example, page 24, lines 1-4 and 13-16, and original claim 4 (referring to the published PCT application).

New claims 32-41 find support in the specification at, for example, page 25, lines 9-13 (referring to the published PCT application).

I. The Claimed Invention is Enabled

Claims 1-6 and 28-31 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. In particular, the Office asserts "it is unpredictable whether the claimed composition is clinically effective for prevention or treatment of a disease, and therefore, it would take undue trials and errors to make and use the claimed invention" (see, page 3 of the Office Action). Applicants traverse the rejection and respectfully request reconsideration thereof because one skilled in the art would not be required to perform undue experimentation to make and use the claimed invention.

As a preliminary matter, the Office appears to continue to mistakenly assert that Applicants' vaccine composition "must possess the properties of a prophylactically or therapeutically effective adjuvant" (see, Office Action dated November 21, 2007 at page 4; emphasis in original). There is absolutely no requirement that Applicants' vaccine composition act as or possess properties of an "adjuvant." Indeed, an adjuvant is, generally, an optional component of a vaccine composition (such as Alum, Freund's adjuvant, etc.) that enhances the immune response generated by the vaccine composition. The vaccine composition elicits an immune response to the peptide antigen contained therein. Thus, the claimed vaccine

composition need not have any "adjuvant" effect. The present Office Action did not specifically address this point. Rather, the Office merely summarized Applicants' rebuttal.

The Office asserts that one of skill in the art understands that the term "vaccine" "implies **clinical** effectiveness in prevention or treatment of a disease" (see, Office Action at page 3; emphasis added). In support of this assertion, the Office provides a copy of Dorland's Medical Dictionary referring to the term "vaccine." As a preliminary matter, the definition of "vaccine" provided by the Office nowhere supports the definition stated by the Examiner. Indeed, Dorland's Medical Dictionary states the following:

> **vaccine** (vak-sēn´) a suspension of attenuated or killed microorganisms (virus, bacteria, or rickettsiae), administered for prevention, amelioration, or treatment of infectious diseases.

Applicants' undersigned representative has failed to locate any portion of this definition which states that a vaccine must have "clinical" effectiveness.

The Office is reminded that because the claimed invention is a composition and not a method of use, any single use of the composition that is enabled fulfills the enablement requirement for the claims. In this regard, Applicants teach at, for example, page 25, lines 4-7 of the specification (referring to the published PCT) that detection and monitoring of the specific immune responses towards the vaccine can be carried out by several methods. Thus, one use of the claimed compositions is to generate an immune response. Applicants teach in Example 6 (see, pages 39-40 of the specification, referring to the published PCT application) that microsomes loaded with Kb-specific OVA peptides induces OVA-peptide responses ***in vivo***. Thus, Applicants' specification enables generation of an immune response *in vivo* using a claimed composition. Moreover, an immune response generated against the heterologous peptide antigen would be expected to make the individual receiving such a composition better. The Office is reminded that the definition of "vaccine" provided by the Office states that a vaccine can be administered for "amelioration" of an infectious disease. "Amelioration" by almost any definition means to make or become better. Thus, Applicants have sufficiently enabled a single use of the claimed compositions. In light of the foregoing discussion, Applicants respectfully assert that the claimed invention is enabled, and request that the claim rejection be withdrawn.

II. The Claimed Invention is Supported by Ample Written Description

Claim 4 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office alleges that "Applicant is not in possession of the recited genus of 'co-stimulatory molecules'" (see, Office Action at page 4). Applicants traverse the rejection and respectfully request reconsideration thereof.

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence of reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). Applicants' specification identifies particular co-stimulatory molecules including, for example, members of the B7 family, B7.1 and B7.2, as well as ICAM-1 (see, page 23, lines 20-21 and page 38, lines 6-8 of the specification). Further, one skilled in the art of vaccines and immune responses is quite well aware of the phrase "co-stimulatory molecule" as a term of art. Indeed, Applicants provide herewith a copy of a page of an Immunology text book published prior to Applicants' present filing date, providing examples of co-stimulatory molecules. Thus, Applicants respectfully assert that one skilled in the art armed with Applicants' disclosure, would appreciate that Applicants were in possession of the genus of co-stimulatory molecules at the time of their invention. Indeed, even the Examiner previously asserted, when referring to the Greenwald reference, that one of skill in the art at the time of the invention was made "aware of the existence of numerous structurally and functionally diverse co-stimulatory molecules" (see, Office Action dated November 21, 2007 at page 5). Further, there is no requirement that one skilled in the art be able to envision "all" possible co-stimulatory molecules to be in possession of the genus of co-stimulatory molecules.

Accordingly, Applicants respectfully assert that the claimed invention is supported by ample written description, and request that the claim rejection be withdrawn.

III. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Office is invited to contact Applicants' undersigned representative at (610) 640-7859 if there are any questions regarding Applicants' claimed invention.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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Enclosure

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